DOCKET NO.: 48378-0003-00-US Application No.: 10/621,711 Office Action dated: August 4, 2006

#### Amendments to the Specification:

# Please amend Paragraph 0048 as follows:

[0001] Preferably, the adhesive polymer formulation comprises a polyacrylate adhesive polymer of the general formula (I):

$$\begin{array}{c|c} & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\$$

wherein x represents the number of repeating units sufficient to provide the desired properties in the adhesive polymer and R is H or a lower (C<sub>1</sub>- C<sub>10</sub>) alkyl, such as ethyl, butyl, 2-ethylhexyl, octyl, decyl and the like. More specifically, it is preferred that the adhesive polymer matrix comprises a polyacrylate adhesive copolymer having a 2-ethylhexyl acrylate monomer and approximately 50-60% w/w of vinyl acetate as a co-monomer. An example of a suitable polyacrylate adhesive copolymer for use in the present invention includes, but is not limited to, that sold under the tradename of <u>DURO TAK Duro Tak</u> 87-4098 by National Starch and Chemical Co., Bridgewater, N.J., which comprises a certain percentage of vinyl acetate co-monomer.

### Please amend Paragraph 0081 as follows:

[0002] Materials:	mg	<u>wt%</u>
Humectant PVP/VA-S630:	9.66	1.25
Skin permeation enhancers:		
DMSO	73.77	9.51
Lauryl lactate (Ceraphyl® 31)	24.59	3.10
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Ethyl lactate	24.59	3.10
Capric Acid	18.54	2.39
Adhesive polymer: <u>DURO TAK</u> <del>Duro Tak</del> 87-409	79.65	
Hormones:		
Levonorgestrel	4.48	0.58
Ethinyl estradiol	2.20	0.28
Backing layer - Scotchpak® 9732 (3M Company)	16 sheets	
Release liner - Scotchpak® 1022 (3M Company)	16 sheets	
TOTAL	775.41 mg	100.00%

#### Please amend Paragraph 0082 as follows:

[0003] Hormones were dissolved and dispersed in a solution comprising PVP/vinyl acetate and the combination of skin permeation enhancers. DURO TAK Duro Tak 87-4098 (33% solid content) adhesive polymer solution was added, and the container was sealed. The solution was stirred using a magnetic stirring bar at approximately 200 rpm at room temperature for 3 hours, to form a homogeneous solution. The stirred solution was deaerated by allowing it to stand without stirring for one hour or until all air bubbles had disappeared. The deaerated solution was coated onto a piece of the backing layer to a thickness of 700 μm, then dried at 60°C for 15 minutes, using a laboratory coating/drying machine (Model LTSV/LTH, Werner Mathis, Switzerland). The dried adhesive polymer matrix was laminated with a piece of release liner of the same size as the backing layer, to form a sheet of THDS. The sheets were cut into dosage units of 15 cm² using a steel rule die and hydraulic press at 4000 psi. Each dosage unit was individually packaged in a paper or foil pouch and stored at 4°C.

## Please amend Paragraph 0085 as follows:

[0004]	Average thickness of adhesive pol	ymer matrix:	100 μm
Average composition of adhesive polymer matrix:			
Compon	ent:	mg per 15 cm <sup>2</sup> patch	wt%

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PVP/VA-S630:	10.0	3.34
<u>DURO TAK</u> <del>Duro Tak</del> 87-4098: Enhancers:	211.3	70.43
DMSO:	24.0	8.00
Lauryl lactate:	25.2	8.40
Ethyl lactate:	4.5	1.50
Capric Acid:	18.0	6.00
Hormones:		
Levonorgestrel	4.7	1.57
Ethinyl estradiol	<u>2.3</u>	0.77
TOTAL:	300.0	100.00